EUROPEAN COMMISSION

DG Competition

Case M. 7559 – Pfizer / Hospira

Only the English text is available and authentic.

REGULATION (EC) No 139/2004

MERGER PROCEDURE

Purchaser approval - Art. 6(1)(b) in conjunction with 6(2)

Date: 04.02.2016

EUROPEAN COMMISSION

Brussels, 04.02.2016
C(2016) 777 final

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

IMPLEMENTATION OF COMMITMENTS

To the notifying party

Dear Sir/Madam,

Subject: **Case M.7559 – Pfizer / Hospira**
Approval of Novartis AG as purchaser of Infliximab Divestment Business following your letter of 23 December 2015 and the Trustee's opinion of 22 January 2016

I. FACTS AND PROCEDURE

1. By decision of 4 August 2015 ("the Decision") based on Article 6(1)b in connection with Article 6(2) of Council Regulation (EEC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings,[1] the Commission declared the operation by which the undertaking Pfizer Inc. ("Pfizer", United States), acquired sole control of the whole of the undertaking Hospira Inc. ("Hospira", United States) (the "Transaction") compatible with the internal market and with the EEA Agreement, subject to full compliance with the conditions and obligations laid down in the commitments annexed to the Decision (the "Commitments").

2. In particular, the Commitments provide that Pfizer will divest, amongst others, the development, manufacturing and marketing rights of its *infliximab* pipeline biosimilar, with a reverse carve-out of ex-EEA development, manufacturing and marketing rights back to Pfizer (together, the "Infliximab Divestment Business").

3. By letter of 23 December 2015, the Parties proposed Novartis AG ("Novartis") for approval by the Commission as purchaser of the Infliximab Divestment

[1] OJ L 24, 29.1.2004, p. 1-22 ("the Merger Regulation").

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Business and submitted the proposed Framework Agreement and related ancillary agreements (the "Proposed Agreements").

4. On 22 January 2016, the Monitoring Trustee, CompetitionRx, member of Mazars group of companies (the "Trustee"), submitted its reasoned opinion on Novartis' suitability as a purchaser of the Infliximab Divestment Business and, in particular, has indicated that it fulfils the criteria set out in Section D of the Commitments attached to the Decision. In this assessment, the Trustee also indicated that, on the basis of the Proposed Agreements, the Divestment Business would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

5. As set out in section D of the Commitments, in order to be approved by the Commission, the purchaser of the Infliximab Divestment Business must fulfil the following criteria:

    a. the purchaser shall be independent of, and unconnected to, Pfizer and its affiliated undertakings (this being assessed having regard to the situation following the divestiture);

    b. the purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the Infliximab Divestment Business as a viable and active competitive force in competition with Pfizer and other competitors;

    c. the acquisition of the Infliximab Divestment Business by the purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Infliximab Divestment Business;

    d. the purchaser shall have a binding agreement with […] (to the extent the purchaser is not […]), […] and […] in relation to *infliximab*;

    e. the purchaser shall have established capabilities in the clinical development of biological medicinal products, with at least one monoclonal antibody in phase III clinical trials for EEA approval;

    f. the purchaser shall have expertise and experience in having relevant interactions with relevant EEA-wide and national bodies that decide on approval of biological medicinal products and on pricing and reimbursement of pharmaceuticals;

    g. the purchaser shall have established capabilities or a track record in the distribution of biological medicinal products in the EEA; and

    h. the purchaser shall have a complementary product portfolio in the clinical areas relevant to *infliximab*.

6. This section provides a short description of the purchaser, as well as an assessment of its suitability in view of these criteria.

Description of the purchaser

7. Novartis is a global healthcare company, headquartered in Switzerland, employing more than 133 000 employees and selling products in more than 180 countries. In 2014, it achieved 37% of its turnover (equivalent to USD 21 billion) in Europe.

8. Novartis' subsidiary Sandoz is the second generic medicines provider globally and the number one in differentiated generics, including medicines that are difficult to develop and manufacture. Sandoz' Biopharmaceuticals business unit, into which the Infliximab Divestment Business will be integrated, is a leading developer of biosimilars, with three biosimilar products currently marketed in Europe.

Independence from Pfizer

9. No shareholders that hold more than 5% in both Pfizer and Novartis' stock. Furthermore, Novartis and Pfizer do not share any executive or non-executive directors.

10. Both Novartis and Pfizer hold a minority shareholding, with right to appoint a board member, in […]. However, none of these companies hold any pharmaceutical in clinical stage (phase I onwards), save for […] which is in […] (an area entirely unrelated to the therapeutic indications of *infliximab*).

11. Finally, the existing commercial relationships between Novartis and Pfizer are not material and have been concluded in the ordinary course of business and at arms-length.

12. In light of the above, the Commission considers that Novartis is independent of and unconnected to Pfizer.

Financial resources, proven expertise and incentive to maintain and develop the Infliximab Divestment Business as a viable and active competitor

13. In 2014, Novartis achieved a net income of USD 10.3 billion. The company's net debt amounts to 8% of the market value of the company's equity.

14. The acquisition of the Infliximab Divestment Business will be financed through Novartis' own resources. The purchase price of […] represents only a small proportion of the company's free cash flow (USD 10.8 billion in 2014) or of the cash and cash equivalents held on Novartis' balance sheet.

15. Novartis has been active in the development of biosimilar products for almost 20 years. Novartis was the first company to have launched a biosimilar product worldwide (in 2006) and today it offers another two biosimilars in Europe. Novartis' experience in developing biosimilars is also evidenced by its portfolio of pipeline biosimilar products.

16. As regards the incentives to develop the Infliximab Divestment Business, Novartis will have invested significant financial resources in order to acquire the product (including an […] upfront payment). Furthermore, the acquisition is in line with Novartis' long-term business strategy since the product is complementary to Novartis' portfolio of monoclonal antibody biosimilars.

17. The Trustee has reviewed Novartis' business plan, and considers that, based on reasonable projections and quite conservative assumptions, the Infliximab Divestment Business shows an attractive net present value and Internal Rate of Return (IRR).

18. In light of the above, the Commission considers that Novartis has the financial resources, proven expertise and incentive to maintain and develop the Infliximab Divestment Business as a viable and active competitive force in competition with Pfizer and competitors on the market.

Absence of *prima facie* competition concerns

19. […].[2]

20. Consequently, no *prima facie* competition concerns arise in the EEA.

21. This *prima facie* assessment is exclusively based on the information provided by Pfizer and Novartis, and does not prejudge the conclusion stemming from a deeper enquiry if and when this proposed concentration is notified to a competition authority, including the Commission.

Binding agreement with […], […] and […] in relation to *infliximab*

22. Novartis has concluded binding agreements with […], […] and […] in relation to *infliximab*, either executed or in final agreed form (to be executed at closing).

23. Furthermore, it should be noted that ultimately Novartis will achieve independence of supply from Pfizer:

    a. […];

    b. […].[3]

24. […].

Established capabilities in the clinical development of biological medicinal products

25. Novartis has developed, obtained approval for and successfully marketed several biologics and biosimilars in Europe. Furthermore, it has a number of pipeline products under development. Its portfolio of marketed biological medicinal products includes *somatropin*, *filgrastim* and *epoetin alfa* biosimilars, as well as the recently approved *secukinumab* (an anti-interleukin-17 monoclonal antibody).[4]

26. Novartis is currently developing several biosimilars, including programs in phase III clinical trials or registration preparation. In particular, Novartis has phase III programmes covering biosimilars of *etanercept*, *adalimumab*, *rituximab*, EPO

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2 Trustee's reasoned opinion, paragraph 40.

3 Trustee's reasoned opinion, paragraphs 188-189, and Novartis' presentation to the case team, slides 15-16 (11 January 2016).

4 Source: European Medicines Agency.

and pegylated-*filgastrim*, as well as […]. Both *adalimumab* and *rituximab* are monoclonal antibodies.

27. The Commission, therefore, concludes that Novartis has established capabilities in the clinical development of biological medicinal products.

Expertise and experience in having relevant interactions with relevant EEA-wide and national bodies that decide on approval of biological medicinal products and on pricing and reimbursement of pharmaceuticals

28. Novartis has a nearly 20 years of experience developing biosimilars and is one of the global leaders in developing, manufacturing and commercialising biosimilars. It has an even longer experience in developing biological pharmaceuticals.

29. The Sandoz business unit has a strong regulatory affairs team working in conjunction with the clinical teams. Most recently, on 8 December 2015, Novartis announced that the European Medicines Agency accepted its marketing authorization application for a proposed *etanercept* biosimilar.[5]

30. The Commission, therefore, concludes that Novartis has expertise and experience in having relevant interactions with relevant EEA-wide and national bodies that decide on the approval of biological medicinal products and on the pricing and reimbursement of pharmaceuticals.

Established capabilitites in the distribution of biological medicinal products in the EEA

31. Novartis' distribution model relies on […]. Novartis' distribution system covers most of the EEA […]. Relying on this model, Novartis has been successfully commercializing an extensive portfolio of pharmaceuticals, including biological medicinal products, across the EEA.

32. The Commission, therefore, concludes that Novartis has established capabilities in the distribution of biological medicinal products in the EEA.

Complementary portfolio

33. Novartis has a complementary product portfolio, including marketed and pipeline products, in the clinical areas relevant to *infliximab*, namely immunological diseases. For example, Novartis is marketing *secukinumab*, a monoclonal antibody which is suitable for treatment of psoriasis, and is tested for the ankylosing spondylitis and psoriatic arthritis indications. It also has an *etanercept* biosimilar under review by the European Medicines Agency, as well as *adalimumab* and *rituximab* biosimilars in phase III clinical trials.[6]

34. The Commission, therefore, concludes that Novartis has a complementary product portfolio in the clinical areas relevant to *infliximab*.

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5 https://www.novartis.com/news/media-releases/sandoz-advances-its-biosimilars-program-european-medicines-agency-ema-acceptance

6 http://www.sandoz-biosimilars.com/en/aboutus/biosimilars-pipeline.shtml

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

35. The Framework Agreement was signed on 22 December 2015 between Pfizer and Novartis' subsidiary Sandoz AG, and subsequently amended on 26 January 2016.

36. The Trustee has provided an assessment of the Proposed Agreements, and confirms that they fulfil the condition of the Commitments to transfer the Infliximab Divestment Business to a suitable purchaser. However, it highlighted in particular the following variations compared to the Commitments:

    a. *Personnel.* Novartis has not taken a decision on the number of employees that it would hire, in particular from the Key Personnel.

    b. *CTA sponsorship.* The Clinical Trial Authorisations will not be transferred to Novartis.

37. The Commission considers that these variations are not liable to impact the viability of the businesses:

    a. *Personnel*. Novartis has indicated that it has the necessary personnel and field force to take over the project, and that it maintains the right to offer employment to the Key Personnel if it later determines that it needs such Key Personnel. Pfizer's Key Personnel will also be providing the necessary expertise and support to Novartis through transitional services in particular.

    b. *CTA sponsorship*. Both Pfizer and Novartis expressed the view that the inherent risks associated with a transfer of the Clinical Trial Authorisations may delay the timeline for the launch of the product (e.g. through delaying the receipt of a marketing authorisation), as well as imperil the integrity of the study.

38. In relation to the Personnel and CTA sponsorship, the Commission therefore concludes that, in accordance with paragraph 19 of the Commitments, the acquisition of the Infliximab Divestment Business by Novartis without any Personnel and without the sponsorship of the CTAs does not affect the viability and competitiveness of the Infliximab Divestment Business after the sale.

39. Based on the above, the Commission concludes that the Infliximab Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

40. On the basis of the above assessment, the Commission approves Novartis as a suitable purchaser of the Infliximab Divestment Business. The Commission further concludes that the Infliximab Divestment Business is being sold in a manner consistent with the Commitments.

41. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreements. This decision does not constitute a confirmation that Pfizer has complied with the Commitments.

42. This decision is based on Section D of the Commitments attached to the Commission Decision of 4 August 2015.

For the Commission
(Signed)

Johannes LAITENBERGER
Director-General